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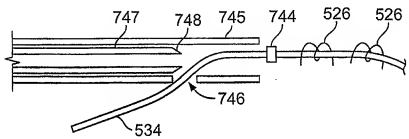

(57) **Abstract:** Devices and methods used in termination of a tissue tightening procedure are described. Termination includes the cinching of a tether to tighten the tissue, locking the tether to maintain tension, and cutting excess tether. In procedures involving anchors secured to the tissue, the tether is coupled to the anchors and the tissue is tightened via tension applied to the anchors by cinching the tether. In general, the devices and methods can be used in minimally invasive surgical procedures, and can be applied through small incisions or intravascularly. A method for tightening tissue by fixedly coupling a first anchor to a tether and slidably coupling a second anchor to the tether, securing both anchors to the tissue, applying tension to the tether intravascularly, fixedly coupling the tether to the second anchor, and cutting the tether is described. The tissue to be tightened can comprise heart tissue, in particular heart valve annulus tissue. Various devices and methods for locking the tether in place and cutting excess tether are described.

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typically involves an open-heart surgical procedure to replace or repair the valve. Valve repair procedures usually involve annuloplasty, which is a set of techniques designed to restore the valve annulus shape and strengthen the annulus. Conventional annuloplasty surgery generally requires a thoracotomy (a large incision into a patient's thorax), and sometimes a median stemotomy (an incision through a patient's sternum). These open-heart, open-chest procedures routinely involve placing the patient on a heart-lung bypass machine for long periods of time so that the patient's heart and lungs can be stopped during the procedure. In addition, valve repair and replacement is typically technically challenging and requires a substantial incision through a heart wall to access the valve. Many patients such as elderly patients, children, patients with complicating conditions such as comorbid medical conditions or those having undergone other surgical procedures, and patients with heart failure, are not considered candidates for heart valve surgery because of the high risk involved.

[0005] Minimally invasive procedures are typically performed endoscopically through catheters, through small incisions or intravascularly. Instruments such as graspers, dissectors, clip appliers, lasers, cauterization devices and clamps are routinely used endoscopically, with an endoscope used for visualizing the procedure. When a surgeon desires to bring pieces of two tissue together, the surgeon typically threads a suture through the two pieces of tissue, applies tension, and ties off or knots the suture to maintain the tension. However, during endoscopic surgery, the manipulation required when knotting or tying suture material can be difficult because of severely restricted space.

[0006] Previously, there have been attempts to maintain tension in tissue by using staples, clips, clamps, or other fasteners to obviate the need for suturing. However, these methods do not provide adjustable tension such as is available when a surgeon uses suture. U.S. Patents Nos. 5,520,702 and 5,643,289 describe deformable cylindrical tubes that can be applied over a loop of suture. After a suture is adjusted to a desired tension, the suture is looped, and a deployment gun applies a deformable tube over the suture loop and crimps it so that it clamps down on the suture. After the loop is secured with a crimp, a separate cutting member or tool can be used to cut the excess suture material. U.S. Patent No. 6,099,553 also describes deformable crimps that can be applied over the ends of sutures to fix them into place. Similar crimping devices that operate to mechanically fasten suture together and cut away excess tether are provided as TI-KNOT® knot replacement systems by LSI Solutions.® However, with crimping schemes, the suture may still slip through crimps and lose tension, especially if the

tissue; locking the cinching tether in place; and cutting off excess tether. Tissue anchors can be secured to the tissue to be tightened and the tether coupled to the anchors, so that cinching of the tether tightens the tissue via the anchors.

[0011] In some variations, a method for tightening tissue is provided. A first anchor is fixedly coupled to a tether, and a second anchor is slidably coupled to the tether. Both anchors are secured to the tissue to be tightened. Tension is applied to the tether intravascularly, the second anchor is fixedly coupled to the tether, and the tether is cut.

[0012] In some variations, the anchors are secured to the tissue intravascularly. In some variations, the tissue includes heart tissue. For example, the tissue can include a heart valve annulus or a mitral valve annulus.

[0013] A force having a component counter to the tensioning force applied to the tether can be applied to the second anchor in some variations. An intravascular device can be contacted with the second anchor to apply the force to the second anchor.

[0014] In some variations, a portion of the tether is loaded into an intravascular device after the anchors are secured to the tissue. The tether can be captured with a loop to load it into the intravascular device. The tether can also be threaded through a feature in a rod, and the rod can be inserted into the intravascular device. The features in the rod can include openings, indents, grooves, slits, or the like.

[0015] In other variations, the tether can be fixedly coupled to the anchor intravascularly. In some variations, the tether is fixedly coupled to the second anchor by clamping the tether to the second anchor. In other variations, the tether can be fixedly coupled to the second anchor by deforming the second anchor. In still other variations, the tether can be fixedly coupled to the second anchor by applying an adhesive to the tether.

[0016] In some variations, the tether is fixedly coupled to the second anchor by providing a locking feature on the tether. The tether can be threaded through a feature on the second anchor, and the locking feature cannot pass through the feature on the second anchor in the direction toward the first anchor. The locking feature can include protrusions that allow the locking feature to slide along the tether in one direction only. The locking feature can include a knot. The locking feature can include a washer through which the tether passes and a knot on the tether, which cannot pass through the washer. In some variations, the locking feature can pass through the feature on the second anchor through which the tether passes in the direction away from the first anchor. The feature on the second anchor can include an eyelet.

variations, the same or different intravascular device may be used to perform any step or combination of steps in a method for tightening tissue that includes securing to the tissue a first anchor fixedly coupled to a tether and a second anchor slidably coupled to the tether, applying tension to the tether intravascularly, fixedly coupling the tether to the second anchor and cutting the tether.

[0022] In some variations, a termination device includes a detachable locking feature and a tether cutter. For example, the termination device may comprise a tubular body that couples to a tether with a detachable locking feature at the distal end of the termination device. The termination device may also include a tether cutter. In some variations, the tether cutter is located proximal to the detachable locking feature. In operation, the tether may be coupled to the detachable locking feature (e.g., by threading through a region of the detachable locking feature), and the locking feature may be positioned to secure the tether (e.g., abutting an anchor). The tether may be tensioned appropriately, and the locking feature can be locked and detached from the rest of the termination device. The tether maybe cut either before or after detaching the locking feature. In some variations, the termination device comprises a rod for locking the detachable locking feature and/or for detaching the detachable locking feature.

[0023] Described herein are termination devices for locking an implantable and cinchable tether. The termination devices may include an elongate body and a locking feature releasably attached to the distal end of the elongate body. The locking feature is typically configured to couple to the tether, and has an unsecured state (e.g., an "open" state in some variations), wherein the tether may move with respect to the locking feature, and a secured state (e.g., a "closed state" in some variations), wherein the tether is secured by the locking feature. The termination device may also include a tether cutter. For example, a tether cutter may be located distally to the locking feature. (such as a cutting tube within the elongate body). In some variations, the elongate body is configured as a catheter.

[0024] In some variations, the termination device may also include a force applicator for releasing the locking feature from the rest of the termination device. For example, the force applicator may comprise a push rod extending longitudinally within the elongate body of the termination device. The termination device may also include a releasable attachment region between the locking feature and the elongate body that can be broken or detached to separate the locking feature of the termination device from the rest of the device. The releasable attachment

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. 1 is a cross-sectional view of a heart with a flexible anchor delivery device being positioned for treatment of a mitral valve annulus, according to some embodiments.

[0030] FIGS. 2A-D are cross-sectional views of a portion of a heart, schematically showing positioning of a flexible device for treatment of a mitral valve annulus, according to some embodiments.

[0031] FIG. 3 is a perspective view of a distal portion of an anchor delivery device, according to some embodiments.

[0032] FIG. 4 is a perspective view of a segment of a distal portion of an anchor delivery device, with anchors in an undeployed shape and position.

[0033] FIG. 5 is a different perspective view of the segment of the device shown in FIG. 4.

[0034] FIG. 6 is a perspective view of a segment of a distal portion of an anchor delivery device, with anchors in a deployed shape and position.

[0035] FIGS. 7A-7E are cross-sectional views of an anchor delivery device, illustrating a method for delivering anchors to valve annulus tissue.

[0036] FIGS. 8A and 8B are top views of a plurality of anchors coupled to a self-deforming member or "backbone," with the backbone shown in an undeployed shape and in a deployed shape.

[0037] FIGS. 9A-9C are various perspective views of a distal portion of a flexible anchor delivery device according to some embodiments.

[0038] FIGS. 10A-10F illustrate a method for applying anchors to a valve annulus and cinching the anchors to tighten the annulus, using an anchor delivery device according to some embodiments.

[0039] FIG. 11 shows a heart in cross-section with a guide catheter device advanced through the aorta into the left ventricle according to some embodiments.

[0040] FIG. 12A-12F illustrate a method for advancing an anchor delivery device to a position for treating a heart valve according to some embodiments.

[0041] FIGS. 13A and 13B are side cross-sectional views of a guide catheter device for facilitating positioning of an anchor delivery device according to some embodiments.

[0042] FIGS. 14A and 14B are illustrative variations of devices and methods for loading tethers into catheters.

[0056] FIGS. 28A-C show examples of termination devices and methods that include threading a tether through a channel of a clamping device, and inserting an actuator that forces actuator elements into the channel to impede slippage of the tether to lock the tether in place.

[0057] FIGS. 29A-F illustrate various examples of termination devices and methods that utilize sharpened tubes to sever excess tether after the tether is locked into place.

[0058] FIGS. 30A-B show additional examples of termination devices and methods that utilize sharpened tubes to sever excess tether.

[0059] FIGS. 31A-D illustrate variations of tubular termination devices and methods that can be used to cut excess tether after the tether is locked into place.

[0060] FIGS. 32A-B show other variations of tubular termination devices and methods for cutting tether.

[0061] FIG. 33 illustrates variations of termination devices and methods that utilize concentric tubes for cutting tether.

[0062] FIGS. 34A-D show variations of termination devices and methods that include a rotatable blade attached to the end of a tube.

[0063] FIGS. 35A-C provides examples of termination devices and methods that include a hook that pulls excess tether over a cutting surface to sever the tether.

[0064] FIGS. 36A-B show examples of termination devices and methods that include the use of angled barbs to cut excess tether.

[0065] FIG. 37 illustrates variations of termination devices and methods in which a cutter attached to an expandable member is used to cut a tether.

[0066] FIGS. 38A-D show examples of various termination devices and methods that involve threading a tether between pins and severing the section of tether extended between the pins.

[0067] FIG. 39 shows one variation of a termination device as described herein.

[0068] FIGS. 40A and 40B show different variations of termination devices.

[0069] FIG. 41A shows a termination device and a loading device for loading a tether into a termination device.

[0070] FIG. 41B shows a termination device with a detachable locking feature.

[0071] FIG. 41C shows the locking feature of FIG. 41B after detaching from the rest of the termination device.

[0072] FIG. 42A and 42B show one variation of a termination device.

example, a heart valve annulus. (In FIGS. 1, 2A and 2B, distal portion 102 is shown diagrammatically without anchors or an anchor-delivery mechanism to enhance clarity of the figures.) In some embodiments, the elongate body comprises a rigid shaft, while in other embodiments it comprises a flexible catheter, so that distal portion 102 may be positioned in the heart H and, for example, under one or more valve leaflets to engage a valve annulus via a intravascular approach. Intravascular access may be gained, for example, through the internal jugular vein (not shown) to the superior vena cava SVC to the right atrium RA, across the interatrial septum to the left atrium LA, and then under one or more mitral valve leaflets MVL to a position within the left ventricle (LV) under the valve annulus (not shown). Alternatively, access to the heart may be achieved via the femoral vein and the inferior vena cava. In other embodiments, access may be gained via the coronary sinus (not shown) and through the atrial wall into the left atrium. In still other embodiments, access may be achieved via a femoral artery and the aorta, into the left ventricle, and under the mitral valve. Any other suitable access route may also be used.

[0077] In other embodiments, access to the heart H may be transthoracic, with delivery device 100 being introduced into the heart via an incision or port in the heart wall. Even open heart surgical procedures may benefit from the disclosed methods and devices. Furthermore, some embodiments may be used to enhance procedures on the tricuspid valve annulus, adjacent the tricuspid valve leaflets TVL, or any other cardiac or vascular valve. Therefore, although the following description typically focuses on minimally invasive or less invasive mitral valve repair for treating mitral regurgitation, the disclosed methods and devices are in no way limited to that use.

[0078] With reference now to FIGS. 2A and 2B, a method for positioning delivery device 100 for treating a mitral valve annulus VA is depicted diagrammatically in a cross-sectional view. First, as in FIG. 2A, distal portion 102 is positioned in a desired location under a mitral valve leaflet L and adjacent a ventricular wall VW. (Again, distal portion 102 is shown without anchors or anchor-delivery mechanism for demonstrative purposes.) The valve annulus VA generally comprises an area of heart wall tissue at the junction of the ventricular wall VW and the atrial wall AW that is relatively fibrous and, thus, significantly stronger than leaflet tissue and other heart wall tissue.

[0079] Distal portion 102 may be advanced into position under the valve annulus by any suitable technique, some of which are described below in further detail. Generally, distal portion

first bend may be created by tensioning a first member to give the distal portion a C-shape or similar shape to conform to the valve annulus, while a second bend may be created by tensioning a second member to articulate the C-shaped member upwards against the annulus. In other embodiments, a shaped expandable member, such as a balloon, may be coupled with distal portion 102 to provide for shape changing/deforming. In various embodiments, any configuration and combination may be used to give distal portion 102 a desired shape.

[0081] For transthoracic methods and other embodiments, distal portion 102 may be pre-shaped, and the method may simply involve introducing distal portion 102 under the valve leaflets. The pre-shaped distal portion 102 may be rigid or formed from any suitable super-elastic or shape memory material, such as nickel titanium alloys, spring stainless steel, or the like.

[0082] In addition to delivering and securing anchors to the valve annulus VA, delivery device 100 (and specifically distal portion 102) may be used to stabilize and/or expose the valve annulus VA. Such stabilization and exposure procedures are described fully in U.S. patent application Ser. No. 10/656,797, which was previously incorporated by reference. For example, once distal portion 102 is positioned under the annulus, force may be applied to distal portion 102 to stabilize the valve annulus VA, as shown in FIG. 2B. Such force may be directed in any suitable direction to expose, position and/or stabilize the annulus. For example, upward and lateral force is shown in FIG. 2B by the solid-headed arrow drawn from the center of distal portion 102. In other cases, only upward, only lateral, or any other suitable force(s) may be applied. With application of force to distal portion 102, the valve annulus VA is caused to rise or project outwardly, thus exposing the annulus for easier viewing and access. The applied force may also stabilize the valve annulus VA, also facilitating surgical procedures and visualization.

[0083] Some embodiments may include a stabilization component as well as an anchor delivery component. For example, some embodiments may include two flexible members, one for contacting the atrial side of a valve annulus and the other for contacting the ventricular side. In some embodiments, such flexible members may be used to "clamp" the annulus between them. One of such members may be an anchor delivery member and the other may be a stabilization member, for example. Any combination and configuration of stabilization and/or anchor delivery members is contemplated.

[0084] Referring now to FIGS. 2C and 2D, an anchor delivery device 108 is shown delivering and securing an anchor 110 to a valve annulus VA. These are again representational

geometry selected to engage and optionally shape or constrict the valve annulus. For example, the rings may be formed from super-elastic material, shape memory alloy such as nickel titanium alloys, spring stainless steel, or the like. In other instances, housing 206 could be formed from an inflatable or other structure that can be selectively rigidified in situ, such as a gooseneck or lockable element shaft, any of the rigidifying structures described above, or any other rigidifying structure.

[0088] "Anchors," for the purposes of this application, is defined to mean any fasteners. Thus, anchors (e.g., anchors 210) may comprise C-shaped or semicircular hooks, curved hooks of other shapes, straight hooks, barbed hooks, clips of any kind, T-tags, or any other suitable fastener(s). In some embodiments, as described above, anchors may comprise two tips that curve in opposite directions upon deployment, forming two intersecting semi-circles, circles, ovals, helices or the like. In some embodiments, anchors (e.g., anchors 210) are self-deforming. By "self-deforming" it is meant that anchors change from a first undeployed shape to a second deployed shape upon release of anchors from restraint in a housing (e.g., release of anchors 210 from housing 206). Such self-deforming anchors may change shape as they are released from a housing and enter valve annulus tissue to secure themselves to the tissue. Thus, for the example shown in FIG. 3, a crimping device or other similar mechanism is not required on distal end 202 to apply force to anchors 210 to attach them to annular tissue. Self-deforming anchors may be made of any suitable material, such as a super-elastic or shape-memory material like a nickel titanium alloy or spring stainless steel. In other embodiments, anchors may be made of a non-shape-memory material and may be loaded into a housing in such a way that they change shape upon release. Alternatively, anchors that are not self-deforming may be used, and such anchors may be secured to tissue via crimping, firing or the like. Even self-securing anchors may be crimped in some embodiments to provide enhanced attachment to tissue. Delivery of anchors may be accomplished by any suitable device and technique, such as by simply releasing the anchors by hydraulic balloon delivery as discussed further below. Any number, size and shape of anchors may be included in a housing.

[0089] In some embodiments, anchors (e.g., anchors 210) are generally C-shaped or semicircular in their undeployed form, with the ends of the "C" being sharpened to penetrate tissue or being blunt, but configured to penetrate tissue when expanded with force. Approximately midway along the C-shaped anchor, an eyelet may be formed for allowing slidable passage of a tether (e.g., tether 212). To maintain anchors 210 in their C-shaped,

"semicircular" refers to a very broad range of shapes including a portion of a circle, a slightly curved line, a slightly curved line with an eyelet at one point along the line, and the like.

[0093] With reference now to FIG. 6, the same segment of distal portion 302 is shown, but mandrels 314 have been withdrawn from two mandrel apertures 322, to release anchors 310 from housing 306. Additionally, expandable member 308 has been expanded to drive anchors out of housing 306. Anchors 310, having been released from mandrels 314, have begun to change from their undeployed, retained shape to their deployed, released shape.

[0094] Referring now to FIGS. 7A-7E, a cross-section of a distal portion 402 of an anchor delivery device is shown in various stages of delivering an anchor to tissue of a valve annulus VA. In FIG. 7A, distal portion 402 is positioned against the valve annulus, an anchor 410 is retained by two mandrels 414, a tether 412 is slidably disposed through an eyelet on anchor 410, and an expandable member 408 is coupled with housing 406 in a position to drive anchor 410 out of housing 406. When retained by mandrels 414, anchor 410 is in its undeployed shape. As discussed above, mandrels 414 may be slidably retracted, as designated by the solid-tipped arrows in FIG. 7A, to release anchor 410. In various embodiments, anchors 410 may be released one at a time, such as by retracting mandrels 414 slowly, may be released in groups, or may all be released simultaneously, such as by rapid retraction of mandrels 414.

[0095] In FIG. 7B, anchor 410 has begun to change from its undeployed shape to its deployed shape (as demonstrated by the hollow-tipped arrows) and has also begun to penetrate the annular tissue VA. Empty mandrel apertures 422 demonstrate that mandrels 414 have been retracted at least far enough to release anchor 410. In FIG. 7B, expandable member 408 has been expanded to drive anchor 410 partially out of housing 406 and further into the valve annulus VA. Anchor 410 also continues to move from its undeployed towards its deployed shape, as shown by the hollow-tipped arrows. In FIG. 7D, anchor 410 has reached its deployed shape, which is roughly a completed circle with overlapping ends or a "key ring" shape. In FIG. 7E, delivery device 402 has been removed, leaving a tethered anchor secured in place in the valve annulus. Of course, there will typically be a plurality of tethered anchors secured to the annular tissue. Tether 412 may then be cinched to apply force to anchors 410 and cinch and tighten the valve annulus. The tether may be cinched using any suitable device or method. For example, during cinching a force can be applied to the most proximal anchor having a vector component counter to the force applied to the tether to cinch the tether. An intravascular device, such as a pusher, may be used to apply this force to the most proximal anchor.

anchor 526 to cause that anchor 526 to exit housing 522 via one of the apertures 528. Contacting member 530 is then pulled farther proximally to contact and apply force to the next anchor 526 to deploy that anchor 526, and so on.

[0099] Retracting contacting member 530 to push anchors 526 out of apertures 528 may help cause anchors 526 to avidly secure themselves to adjacent tissue. Using anchors 526 that are relatively straight/flat when undeployed allows anchors 526 with relatively large deployed sizes to be disposed in and delivered from a relatively small housing 522. In some embodiments, for example, anchors 526 that deploy into a shape approximating two intersecting semi-circles, circles, ovals, helices, or the like, and that have a radius of one of the semi-circles of about 3 mm may be disposed within a housing 522 having a diameter of about 5 French (1.67 mm), or about 4 French (1.35 mm), or even smaller. Such anchors 526 may measure about 6 mm or more in their widest dimension. These are only examples, however, and other larger or smaller anchors 526 may be disposed within a larger or smaller housing 522. Furthermore, any convenient number of anchors 526 may be disposed within housing 522. In some embodiments, for example, housing 522 may hold about 1-20 anchors 526, or about 3-10 anchors 526. Other embodiments may hold more anchors 526.

[0100] Anchor contacting member 530 and pull cord 532 may have any suitable configuration and may be manufactured from any material or combination of materials. In alternative embodiments, contacting member 530 may be pushed by a pusher member to contact and deploy anchors 526. Alternatively, any of the anchor deployment devices and methods previously described may be used.

[0101] Tether 534, as shown in FIG. 9B, may comprise any of the tethers 534 or tether-like devices already described above, or any other suitable device. Tether 534 is generally fixedly coupled to a distal-most anchor 526 at an attachment point 536. By "fixedly coupled," here it is meant that tether 534 is coupled to distal-most anchor 526 in a manner that prevents tether 534 from sliding through or past distal-most anchor 526 in the direction of more proximal neighboring anchors 526. This may be achieved, for example, via a knot, weld, adhesive, or by any other suitable mechanism that fixedly couples tether 534 to distal-most anchor 526. Fixedly coupling includes, for example, via a knot, protuberance, or other feature on tether 534 that cannot pass through an eyelet, loop, or other similar feature in distal-most anchor 526 through which tether 534 passes. Tether 534 then extends through an eyelet, loop or other similar feature on each of the anchors 526 so as to be slidably coupled with the anchors 526. In the

550 is generally a flexible elongate catheter which may have one or more curves or bends toward its distal end to facilitate placement of the distal end of catheter 550 in subannular space 552. The distal end of guide catheter 550 may be configured to be positioned at an opening into or within subannular space 552 such that subsequent catheter devices may be passed through guide catheter 550 into space 552.

[0105] In FIGS. 12A-12F the mitral valve MV, including mitral valve leaflets MVL, is represented diagrammatically from an inferior perspective looking up. In FIG. 12A, guide catheter 550 is show extending up to or into subannular space 552, as in FIG. 11. As shown in FIG. 12B, a second guide catheter 554 may be advanced through first guide catheter 550 to pass through/along a portion or all of subannular space 552. In one embodiment this second guide catheter 554 is steerable (as described below with respect to FIGs 13A and 13B, for example), to help conform second guide catheter 554 to subannular space 552.

[0106] Next, as shown in FIG. 12C, a guide sheath 556 may be passed over second guide catheter 554 to extend along subannular space 552. Sheath 556 is generally a flexible, tubular member that can be passed over second guide catheter 554 and within first guide catheter 550. To enhance passage and exchange, any of these and other described catheter members, sheath members, or the like may be manufactured from and/or coated with one or more friction resistant materials. Once sheath 556 is in place, second guide catheter 554 may be withdrawn, as shown in FIG. 12D. As shown in FIG. 12E, an anchor delivery device 520 (described above) may then be advanced through sheath 556 to a desired position within subannular space 552. Sheath 556 may then be withdrawn, as in FIG. 12F, leaving anchor delivery device 520.

[0107] These are only exemplary methods for advancing an anchor delivery device to a position for treating a valve annulus, and any other suitable method or combination of devices may be used to position an anchor delivery device. In various alternative embodiments, one or more steps may be added, deleted or modified while achieving a similar result. In some embodiments, a similar method may be used to treat the mitral valve from a superior/right atrial position or to treat another heart valve. Additionally, other devices or modifications of the systems just described may be used in other embodiments.

[0108] Referring now to FIG. 10A, anchor delivery device 520 is contacted with the valve annulus VA such that openings 528 are oriented to deploy anchors 526 into the annulus. Such orientation may be achieved by any suitable technique. In some embodiments, for example, a housing 522 having an elliptical cross-sectional shape may be used to orient openings

within the coronary sinus, in proximity to the first magnet. The two magnets may attract one another, thus pulling the anchor delivery device into greater contact with the annulus. Various embodiments may also include visualizing the annulus using a visualization member coupled with or separate from the anchor delivery device. In some embodiments, the tether is a strip of detachable, biocompatible material, such as DACRON® polyester, that is coupled with the anchor delivery device. The anchors are driven through the strip, which detaches to affix to the valve annulus via the anchors. In other embodiments, the tether is a detachable, biocompatible, distal portion of the guide sheath through which the anchors are driven, and that portion of the guide sheath remains attached to the annulus via the anchors.

[0113] Referring again to FIG. 10F, after the plurality of tethered anchors 526 has been secured to the valve annulus, tension may be applied to tether 534 to cinch tether 534 and thereby tighten the annulus, thus reducing valve regurgitation. In some embodiments, valve function may be monitored by any suitable method, such as echocardiogram and/or fluoroscopy, and tether 534 may be cinched, loosened, and adjusted to achieve a desired amount of tightening as evident via the employed visualization technique(s) or monitored function(s). When a desired amount of tightening is achieved, tether 534 is then fixedly coupled to a most-proximal anchor 526 (or to two or more most-proximal anchors 526), using any suitable technique. By "fixedly coupled," here it is meant that tether 534 is coupled to most-proximal anchor or anchors 526 in a manner that prevents tether 534 from sliding through or past most proximal anchor or anchors 526 in the direction of more distal anchors 526. Suitable techniques for fixedly coupling tether 534 to most proximal anchor or anchors 536 include but are not limited to use of adhesives, tying, knotting, crimping the anchor, deforming the anchor, clamping the tether to the anchor, and providing a locking feature on the tether that, for example, cannot pass through an eyelet, loop, or other similar feature in the most proximal anchor or anchors. Some of these techniques are discussed in additional detail below.

[0114] Still referring to FIG. 10F, after tether 534 has been fixedly coupled to most proximal anchor or anchors 526, tether 534 is cut proximal to the most-proximal anchor 526, thus leaving the cinched, tethered anchors 526 in place along the valve annulus VA. Tether 534 may be cut via any technique such as, for example, with a cutting member coupled with housing 522. Techniques and devices for cutting tether 534 are discussed in additional detail below.

[0115] In some embodiments it may be advantageous to deploy a first set of anchors 526 along a first portion of a valve annulus VA, cinch the first set of anchors to tighten that portion

a tube, an elongate element with hole, or any other structure or material that can "grab" the tether.

[0119] In other embodiments (e.g., FIGS. 15A-15H) the tether is loaded into a termination device by threading the tether through one or more features in a rod and then inserting the rod into the termination device. These rods may be of a length that facilitates easy handling, if applicable, and sized to interface with the termination device. Preferably, the rods are 60-150 cm. The rods may be composed of any material which will perform the function of handling the tether, including metal and plastic (e.g., nylon, PEBAX, PEEK, Fluoro polymer like PTFE, PET, or polyethylene, polypropylene, or metal braided polymer). The features in the rod may be, for example, holes, openings, indents, grooves, and slits. The rod may remain in the termination device or be subsequently removed. In some implementations a knot may be tied at the proximal end of the tether to prevent the tether from slipping out of the rod. In some implementations the rod has a passage from one end of the rod to a first opening in a side of the rod and another passage from the other end of the rod to a second opening in a side of the rod. The tether may be threaded through these passages. In FIG. 15A, for example, rod 610 comprises a tube 612 with side holes 614. Tether 534 is threaded through one end of the tube, through the two side holes, and through the other end of the tube. Rod 610 is then inserted into termination device 600 (FIG. 15B).

[0120] In other implementations, (FIG. 15C), rod 616 comprises a C-shaped feature 618 through which tether 534 may be threaded. Rod 616 is then inserted into a termination device similarly to the example shown in FIG. 15B. Feature 618 may be, for example, a C-shaped fastener that snaps around tether 534. In these implementations, tether 534 may comprise a knot or other suitable feature 620 that cannot pass through C-shaped feature 618, thus improving the ability of rod 616 to pull tether 534 into a termination device.

[0121] In the implementations shown in FIGS. 15D-15F, rod 622 comprises through-holes 624 oriented approximately perpendicular to a long axis of the rod and flat portions 626 and 628 oriented approximately parallel to the long axis of the rod. Tether 534 runs along flats 626 and 628 when it is threaded through holes 624. This configuration allows rod 622 and tether 534 to remain within a round profile. In the implementation shown in FIGS. 15G and 15H, rod 630 comprises holes 632 oriented approximately perpendicular to a long axis of the rod and grooves 634 oriented approximately parallel to the long axis. Tether 534 runs along grooves 634 when threaded through holes 632. In these implementations also, the rod and tether may remain

tether 534 in a distal direction until it reaches or is close to the most proximal anchor. Tie 711 is pulled to slide through 713 to tighten the knot around tether 534 such that the tether is locked in place and will not slip past the most proximal anchor, e.g., through an eye of the most proximal anchor. Many different types of slip knots may be used, including Roeder's knots. In some variations, a secondary slip knot can be applied to the end, slipping portion and/or non-slipping portion of tie 711 to further lock knot 712 in place. Tie 711 can be passed inside a catheter 713. In another variation, tether 534 and tie 711 are joined with knots, including half knots, to further lock knot 712 in place.

[0126] In other variations, as shown in FIG. 16B, tether 534 can be looped through anchors 526, with a slip knot 715 positioned near most proximal anchor closing the loop. Tether 534 can be looped through the eye of most distal anchor and then threaded through other anchors in any suitable fashion that allows tension on the tether 534 to be adjusted as necessary. For example, as illustrated in FIG. 16B, tether 534 can be looped through most distal anchor, then both strands can be threaded through the remaining anchors, except for the most proximal anchor. On the most proximal anchor, just one of the strands may be threaded through, while the other strands goes around the last anchor. Thus, the anchor forces the two strands of the knot to exit at angles relative to one another so that when tension is exerted on those strands, a knot such as the Roeder's knot self tightens. Slip knot 715 can be pushed to cinch tether 534 as desired and lock tether 534 into place. A knot pusher can be used to simultaneously cinch and push the knot. As the knot is pushed, tether 534 adjusts, sliding through the most distal anchor such that two sides of the loop of tether 534 are approximately equal in length. The force of tissue expanding outward can cause knot 715 to tighten further. For the most distal anchor, tether 534 can be threaded through a guided feed (not shown), such as a slotted device coupled to most distal anchor, to lessen friction as the tether 534 is cinched. A secondary tie having a secondary slip knot, for example, similar to tie 711 as shown in FIG. 16A, can be applied to tether 534 to help tighten knot 715. In addition, two knots (not shown) can be used for the variation shown in FIG. 16B. The tether can include a loop having a first slip knot positioned proximal the most proximal anchor and a second slip knot positioned distal the most distal anchor. The two slip knots positioned at opposite ends of the plurality of tethered anchors can be used to adjust the length and tension in the loop of the tether.

[0127] In other variations illustrated in FIG. 16C, tether 534 can be threaded through all anchors 526 except the most proximal anchor 626. At the distal end of tether 534 is a block 716,

anchors. The two tethers can then used to make a half knot. Tube 727 can be pushed against half knot 721 to push the knot in a distal direction to create a fully locked knot, holding the tethers in place. Tube 727 can have a saddle (not shown) to aid in pushing. In some variations, the cinching tether or tethers can exit the side of pushing tube 727.

[0130] As shown in FIG. 17A, tether 734 can have protrusions 703 that allow tether 734 to slide through anchors 726, e.g., through anchor eyelets, in one direction, but not in the opposite direction. Protrusions 703 can be arrow-shaped, V-shaped, cone-shaped, triangular, or have any other suitable shape or geometry that allows them to pass in one direction through an opening but not in the reverse direction. Alternatively, protrusions 703 can comprise other shapes or objects, such as knots. In some variations, as shown in FIG. 18A, the most proximal anchor 726' has an eyelet with a reduced cross-sectional dimension such that protrusions 703 can pass as tether 734 is pulled in a proximal direction through the eyelet of anchor 726', but not when tether 734 is pulled in a distal direction. Tether 734 can be ratcheted into a desired tension as sequential protrusions 703 are passed through the most proximal anchor 726'. In other variations, as shown in FIG. 18B, a collar 705 is positioned along tether 734 proximal to most proximal anchor 726'. Tether 734 is threaded through an opening 706 in collar 705. Opening 706 can expand slightly such that protrusions 703 can pass through opening 706 when they are pulled through in a proximal direction, but not when pulled in a distal direction. For example, opening 706 can be a generally fixed opening and protrusions 703 can be of such a shape as to pass in the proximal direction through opening 706 but not in the distal direction. Thus, as sequential protrusions 703 are passed through opening 706, tether 734 is cinched tighter and locked into place.

[0131] Protrusions 703 can be of any type and provided by any suitable method. For example, tether 734 including protrusions 703 can be formed of sheet metal, and then processed, e.g., by electropolishing or any other suitable technique, to remove sharp corners and edges. Tether 734 and protrusions 703 can also be formed of plastic, e.g., a plastic comprising a TEFLON® fluoropolymer, or polyester. Alternatively, protrusions 703 can be added to tether 734 in a separate step, e.g., by threading cones onto a suture and fixing the cones in place along the suture at defined intervals. The cones can be bonded or otherwise attached to or coupled with the suture.

the force to clamp the tether between the surfaces. In some variations, the surfaces of the clamp jaws will be at least partially roughened, toothed, or made to have adhesive properties to hold the tether. For example, as illustrated in FIG. 20A, two sides of a clamp 880 can form an interlocking profile 882, e.g., a stepped profile or other profile having corners. Tether 534 is threaded through holes 881 such that tether 534 traverses profile 882 when clamp 880 is open. As clamp 880 is closed, tether 534 is forced to follow the tortuous path imposed on it by the interlocking profile 882. Clamp 880 can be closed by any suitable mechanism, such as with a closure, or with a spring hinge. If clamp 880 is closed by a spring hinge, it can be propped open using a propping element (not shown) while tether 534 is threaded through holes 881, and before it is desired to fix tether 534 into place. When it is desired to lock down tether 534 during termination, the propping element can be removed. Alternatively, a spring hinge can have an open position, allowing tether 534 to slide freely through clamp 880. When it is desired to fix the tether, the spring hinge can be snapped into a closed position. Clamp 880 can have any suitable interior surfaces 883 such that when the clamp is closed, surfaces 883 prevent tether 534 from slipping. In other embodiments, the clamp can have numerous structural features along its length. For example, as illustrated in FIG. 20B, clamp 1100 has a saw-toothed surface on inner surfaces of both jaws 1110 and 1112 along its longitudinal axis, and tether 534 is threaded through clamp 1100 along its longitudinal axis. Clamp jaws 1110 and 1112 can be locked together when it is desired to fix tether 534 upon termination by any suitable mechanism, such as by using a hinge or clamping mechanism. Besides the stepped surface illustrated in FIG. 20A and the saw-toothed surface illustrated in FIG. 20B, other suitable clamping surfaces can be used, including roughened, notched, etched, scored, and the like.

[0135] FIG. 21A illustrates additional examples of toothed clamping devices that can be used to lock the tether during termination. In FIG. 21A, clamp 885 having first side 886 with protruding features 887 attached thereto and second opposing side 888 with protruding features 889 attached thereto is provided. Protruding features 887 and 889 are placed in an alternating manner along the long axis A-A' of clamp 885 and extend into the interior volume of clamp 885 such that the only path down the long axis is tortuous when clamp 885 is closed. When clamp 885 is opened (FIG. 21B), a generally unobstructed path down the long axis A-A' of the interior of clamp 885 exists. Thus tether 534 can be threaded through axis A-A' of clamp 885 in its opened state. When clamp 885 is closed (FIG. 21C), tether 534 will be forced in a tortuous path by protrusions 887 and 889, and will thus be fixed into place. In some variations, the rest state

illustrated in FIG. 22 can be used either to clamp directly onto tether 534 or to clamp tether 534 to most proximal anchor.

[0139] Clamping devices with expandable, deformable mesh may be used to clamp tethers during termination. Examples of such clamping devices are illustrated in FIG. 23A-C. As shown in FIG. 23A, expandable member 901, e.g., a balloon, encased or partially encased in an expandable mesh element 902 is provided within tube 900, e.g., a catheter. Tether 534 is threaded between inner wall 903 of tube 900 and outer wall 904 of expandable mesh element 902. As shown in FIG. 23B, as expandable member 901 is expanded, tether 534 is compressed between mesh outer wall 904 and tube inner wall 903. In some variations, it may be desired to provide a mesh element having a textured surface, roughened surface, or adhesive properties to increase friction with tether 534. For example, as illustrated in FIG. 23C, mesh element 902 having flanges or other protruding features 905 can be provided that is capable of catching and/or compressing tether 534. Mesh element 902 can be made of any suitable material, e.g., metal, polymer, or any suitable type of fiber, and can have a tubular, or any other suitable, configuration. Tube 900 can be made of any suitable material, and can be rigid or flexible. For example, tube 900 can include an elastomer. Inner wall 903 of tube 900 can be coated with an elastomer or adhesive. The walls of tube 900 can be interrupted, e.g., by providing holes with which the metal mesh can interact, e.g., by at least a partially interlocking interaction. In some variations, the mesh is self-expanding. In these variations, expandable member 901 may be omitted. A sleeve (not shown) may be installed around self-expanding mesh to constrain the outer diameter of the mesh. When the sleeve is removed, e.g., by retraction, the mesh is able to expand outwardly to lock tether 534 between the mesh and tube 900. Self-expanding mesh may be made of materials such as shape-memory metals or superelastic metals.

[0140] A hollow locking element having features that protrude towards its interior can be used to fix tether 534 during termination. An example of such a locking element 930 is provided in FIG. 24A. Tether 534 is threaded through hollow locking element 930. Features 931, such as barbs, flaps, or prongs, protrude inwardly. An inner cross-sectional dimension of element 930 is small enough such that at least some of features 931 contact tether 534 as it is threaded through element 930. Features 931 are angled in a proximal direction, such that locking element 930 can be slid in a distal direction until it reaches or is close to most proximal anchor 526. Because features 931 are angled in a proximal direction, and at least some of features 931 contact tether 534, motion in the opposite direction (i.e., sliding element 930 in a proximal

Material for rings 1024, 1034 can be chosen for any desired property, such as deformability, biocompatibility, or coefficient of friction with the material used for tether 534. In other variations, the tether can be clamped by altering a path of the tether through a locking feature to increase the frictional forces on the tether. For example, the tether can be threaded through a network of rollers or pins to lock the tether in place during termination.

[0142] As shown in FIGS. 28A-B, clamps containing actuated clamping elements can be used to lock the tether in place during termination. For example, clamp 1060 containing clamping elements 1064 and 1066 can be used. Clamp 1060 has first side wall 1062 with a profiled inner surface 1072 and opposite side wall 1068. Actuator channel 1074 is provided between side wall 1068 and elements 1064 and 1066. Elements 1064 are arranged generally collinearly with and alternated with elements 1066 along a length of clamp 1060, such that elements 1064 protrude further into actuator channel 1074. Tether 534 is threaded through channel 1076 between elements 1064, 1066 and profiled inner surface 1072 of first side wall 1062. As actuator 1070 is forced into actuator channel 1074, actuating elements 1064 are preferentially pushed into channel 1076, creating a tortuous path for tether 534 that is threaded through channel 1076 (FIG. 28B). In some cases, actuating elements 1064 have rounded edges where actuator 1070 will slide against them to force them into channel 1076. Profiled inner surface 1072 can have any suitable profile to lock tether 534 during termination. In some variations, a locking device made from a single piece can be used to accomplish the same locking principle as exemplified in FIGS. 28A-B. For example, as shown in FIG. 28C, locking device 1080 can be used. Locking device 1080 comprises a first side wall 1082 having first profiled inner surface 1092. Middle wall 1084 having second profiled inner surface 1090 is provided opposite first inner surface 1092. Second side wall 1086 is provided, separated from middle wall 1084 by actuator channel 1087. Tether 534 is threaded through channel 1084 between surfaces 1090 and 1092. Before locking device 1080, tether 534 can move feely through channel 1084. When it is desired to lock tether 534 using device 1080, an actuator 1091 can be inserted into actuator channel 1087, forcing profiled surfaces 1090 and 1092 together, thus creating a tortuous path for tether 534, and preventing it from slipping through device 1080.

[0143] Adhesive may be used to facilitate the locking of the tether. For example, drops of adhesive material may be applied, e.g., released from an applicator, to bond the tether to any locking mechanism. For example, adhesive may be applied to knots (see FIGS. 16A-E, for

variations may be used for example when tube 747 is spun or rotated during the cutting process. In some variations, as shown in FIG. 29F, cutting tube 747 can be positioned in front of hole 746 such that cutting tube 747 can be pulled in a proximal direction toward hole 746 to cut tether 534 (indicated by solid arrow).

[0146] Alternatively, a cutting tube can be provided that is external to a catheter housing tether 534. For example, as shown in FIG. 30A, tether 534 extends through catheter 745 and exits through hole 746. Again, tether 534 can be loaded into catheter 745 by any suitable method, including methods described herein. Cutting tube 750, which can be a sharpened metal tube, can slide along the exterior of catheter 745. In some variations, cutting tube 750 is attached to a second tube 751 which slides along the exterior of catheter 745. Second tube 751 can be flexible. As cutting tube 750 is advanced in a distal direction toward hole 746 (indicated by solid arrow), end 753 of tube 750 can sever tether 534. As shown in FIG. 30B, a base 754 can be positioned along catheter 745 such that tether 534 is pushed against base 752 as cutting tube 750 is advanced toward hole 746, thereby improving the cutting process. As also shown in FIG. 30B, a cover or shroud 754 can be provided around cutting tube 750 in some variations to prevent sharpened end 753 from catching on tissue or the like. In some variations, cover 754 is attached to second tube 751.

[0147] Cutting tubes can have any suitable shape. For example, as shown in FIG. 31A, cutting tube 760 can have a V-shape along its perimeter or other notched feature designed to channel tether 534. Alternatively, cutting tube 760 can have a curved profile (FIG. 31B), an angled profile (FIG. 31C), a serrated profile (FIG. 31D), or a saw tooth profile (not shown). The latter two variations may be useful when cutting tube 760 is rotated or spun during the cutting process. In some variations, the perimeter of hole 746 is sharpened to cut tether 734. The cutting tubes can be configured such that they operate either externally or internally to catheter 745.

[0148] In some variations, cutting tubes can sever the tether by cutting in a direction roughly perpendicular to the long axis of the catheter, e.g., by rotating one concentric tube relative to a second concentric tube. As illustrated in FIG. 32A, tether 534 enters catheter 745 and exits through hole 746. Cutting tube 770 can be configured such that when it is rotated about the long axis A-A' of catheter 745, it can slice tether 534. For example, cutting tube 770 can have an angled shape such that when it rotates about axis A-A' it cuts tether 534. In some variations, cutting tube 770 is attached to a flexible tube 771. In other variations, a blocking

mounted either external or internal to catheter 792. For example, one tube can be external while the other is internal.

[0152] In some variations, as illustrated in FIG. 35A, a hook, loop or the like can be used to engage the tether between the most proximal anchor and the distal end of the catheter. Tether 534 is cinched, locked into place by locking feature 744, and threaded lengthwise through catheter 801 in channel 807 between an inner wall of catheter 801 and cutting tube 802. Cutting tube 802 has a sharpened edge 803 on its distal end. Assembly 804 having hook 805 on its distal end is configured such that it extends through cutting tube 802. Hook 805 engages a portion 806 of the excess tether that extends proximally from locking feature 744. The length of tether 534 threaded through channel 807 is pulled in a proximal direction. Hook 805 can pull portion 806 of tether 534 in a proximal direction (indicated by solid arrow), forcing the tether against sharpened edge 803, which severs the excess tether. Alternatively, hook 805 can include a sharpened edge or blade such that it can cut tether 534.

[0153] As described above, the tether cutter may comprise any appropriate structure or material. For example, in addition to the cutting tubes described above, the tether cutter may cut by heat, electricity, chemical reaction, or the like. For example, the tether cutter may comprise an electrode or filament through which electrical energy may be applied to cut the tether.

[0154] In other variations, as illustrated in FIG. 35B, tether 534 can be threaded through a collet 810 comprising a housing 811. Housing 811 can be coupled to catheter 817. Tether 534 is threaded through collet 810 such that a loop 812 of tether 534 extends in a proximal direction from collet 810. Collet 810 can have any suitable shape, e.g., U-shaped or C-shaped. A hook or loop 813 coupled to apparatus 815 can be used to engage loop 812. A pusher 814 can be used to apply force in a distal direction to collet 810 while hook 813 is pulled in a proximal direction by apparatus 815. As hook 813 is pulled in a proximal direction, tether 534 is forced against cutting blade 818. Cutting blade 818 can have any suitable orientation or configuration such that tether 534 can be forced against a cutting surface of cutting blade 818. Cutting blade 818 can be attached to, part of, or integral with housing 811. Optionally, a collar 816 can be placed between collet 810 and pusher 814 to aid in applying force to collet 810. In some variations, collet 810 can be placed internal to catheter 817, and housing 811 can be omitted. In those variations, catheter 817 can comprise a cutting blade (not shown) attached to, part of, or integral with the catheter and configured such that as loop 812 of tether 534 is pulled in a proximal direction, tether 534 is forced against the cutting blade. In some variations, hook 813 can be capable of

FIGS. 35D-E, cutting edges 829, 833 can be configured in any suitable manner, e.g., they may be sharpened blades, comprise a serrated cutting edge, or comprise teeth.

[0158] As shown in FIG. 37, a cutter can be mounted on a balloon within a catheter. An excess portion of tether 534 proximal to locking device 755 enters catheter 837 at its distal end and exits through side hole 831. Expandable member 832 is provided within catheter 837 and is adjacent to the section of tether 534 within catheter 837. Expandable member 832 can be, for example, a balloon, or more than one balloon. Attached to the perimeter of the expandable member are cutters (e.g., blades) 838 capable of cutting tether 534. Expandable member 832 can be expanded such that tether 534 is pressed between an interior wall of catheter 837 and cutter 838. When in its expanded state, expandable member 832 can be rotated along an axis generally parallel to the long axis of catheter 837 to cut tether 534. For example, if expandable member 832 comprises a balloon, the balloon can be inflated to an amount such that cutter 838 is pressed against tether 534 but the balloon can still be rotated within catheter 837. Cutter 838 can have any suitable shape or configuration. In some variations, a single blade 838 can be attached to expandable member 832 that is capable of cutting tether 534. In other variations, cutter 838 can sever tether 534 by virtue of the blade being pressed into the tether by the expandable member, and thus need not be rotated to a substantial degree to sever tether 534. In some variations, a deformable mesh tube (not shown) can be provided to at least partially encase expandable member 832. Thus, as expandable member 832 is expanded, it can cause the mesh tube to expand against tether 534, sandwiching it between the mesh and tube 837 to hold tether 534 in place.

[0159] As shown in FIGS. 38A-D, tether 534 can be threaded through cutting apparatus 839 comprising a guillotine-like blade and an opposing cutting block. The excess portion of tether 534 proximal locking device or mechanism 744 is threaded into catheter 840 between side wall 841 and pin 842. Tether 534 then traverses part of the inner diameter of catheter 840 and is threaded between opposite side wall 843 and pin 844. Blade 845 is provided on one side of portion 847 of tether 534 extended between pins 842 and 844. Blade 845 is mounted in any suitable manner, e.g., on a bridge 848 at least partially within catheter 840. Optionally, a cutting block 846 is provided across tether portion 847 and opposite blade 845. As tension is applied to tether 534 in a proximal direction (indicated by solid arrow), blade 845 can be forced against tether portion 847, thus severing the tether. Blade 845 can cut against cutting block 846, when present. As shown in FIG. 38C, a tool comprising a pair of blades connected with a pivot (e.g., a

[0162] For example, with reference to FIGS. 23A-C, a balloon or other expandable member 901 can be inflated to expand a metal mesh 902 to clamp tether 534 between mesh 902 and an outer tube 900. Subsequently, a sharpened tube can be advanced to cut the tether. For example, if the tether is threaded through a side hole, the sharpened tubes that are provided in FIGS. 30A-B, 31A-D, and 32A-B can be used to cut the tether as indicated in the figures. If the tether is not threaded through a side hole, cutters such as are illustrated in FIGS. 34A-D can be used. Any suitable cutting technique can be also be used to sever the excess tether.

[0163] In another example, with reference to FIG. 37 and FIGS. 23A-C, the expandable member or balloon 832 of FIG. 37 can be inflated to expand a metal mesh (not shown in FIG. 37 but similar to mesh 902 as illustrated in FIGS. 23A-C) to compress the tether 534 between the mesh and outer tube 837. Cutting mechanism 838 is mounted to expandable member 832. Expandable member 832 can be configured such that the portion of the expandable member to which cutter 838 is mounted inflates after the metal mesh is expanded. For example, expandable member 838 can comprise two separate balloons, one of which has cutting mechanism 838 attached thereto. When the portion of member 832 comprising cutter 838 is expanded, cutter 838 cuts tether 534. Alternatively, a cutter or cutters 838 can be rotated to sever tether 534. Once the tether has been cut, the mesh locking mechanism applied to the tether can be released, e.g., by advancing a pusher (not shown).

[0164] In another example of an architecture of a termination device, with reference to FIG. 37 and FIGS. 16A-E, a multi-stranded half-knot in tether 534 can be pushed down to lock tether 534 in place. Then expandable member can be inflated and rotated at least partially within catheter 837 such that cutters (e.g., blades) 838 cut tether 534. Alternatively, with reference to FIGS. 30A-B, 31A-D, 32A-B, 33, and 34A-D as examples, any type of tube-mounted cutter can be used to sever tether 534. For cutting devices such as those illustrated in FIGS. 30A-B, 31A-D, 32A-B, and 33, in which tether 534 is threaded through a side hole (e.g., side hole 746 in FIGS. 30A-B) to enable cutting, additional tethers or cables used to form multi-stranded knot 721 can also be threaded through the side hole and cut. Any other type of cutting mechanism described herein can be used in combination with a tether locking mechanism employing a multi-stranded half-knot to fix tether 534.

[0165] With reference now to FIGS. 13A and 13B, one embodiment of a steerable catheter device 560 is shown. Steerable catheter device 560 may be used in a method such as that just described in reference to FIGS. 12A-12F, for example in performing a function similar

tensioning member 568 in various embodiments. For example, shaped expandable members, shape memory members and/or the like may be used to change the shape of distal portion 564.

[0167] Generally, proximal portion 562 of the catheter body is less flexible than distal portion 564. Proximal portion 562 may be made of any suitable material, such as PEBAX® elastomers, fluoroethylenepropylene, nylon, polyethylene and/or the like, and may include a braided material, such as stainless steel, to provide stiffness and strength. Distal portion 564 may be made of similar or other materials, but the braided material is typically not included, to provide for greater flexibility. Both proximal and distal portions 562/564 may have any suitable lengths, diameters, overall configurations and the like. In one embodiment the catheter body is approximately 140 cm in length and 6 French in diameter, but any other suitable sizes may be used in other embodiments. Proximal portion 562, distal portion 564 or preferably both, may be made from or coated with one or more friction resistant or lubricating material to enhance passage of device 560 through an introducer catheter and/or to enhance passage of a sheath or other device over catheter device 560.

[0168] As described above, the termination devices described herein may be integrated termination devices, including tether cutters, locking features, tensioning devices, positioning devices, and the like. Provided below are exemplary termination devices including many of these features.

Examples

[0169] In general, termination devices are designed to cinch, lock, and/or cut a tether (e.g., a suture or cable) as described herein. These devices can be used for any surgery where these functions (or combinations of them) are desired. FIG. 39 shows a termination device 3901 having a detachable locking feature 3905 that is releasably attached at the distal end of the termination device. This variation of a termination device has an elongated tubular body 3903 which may be flexible over all (or a portion) of its length. Thus, the termination device may be used in non-invasive procedures (e.g., percutaneously) or in invasive (e.g., open-heart) surgeries. The termination device shown in FIG. 39 is configured as a termination device catheter.

[0170] The termination device 3901 shown in cross-section in FIG. 39 is coupled to a tether 3910. The tether is threaded through the distal region of the termination device, particularly through the locking feature 3905 region at the distal end of the termination device. Although any locking feature may be included as part of the termination device, as described

rod from being pushed too far forward, or applying too much force, which could disturb either the locking mechanism or the tissue (e.g., after separation of the locking mechanism from the rest of the termination device).

[0173] The locking feature may be detachably connected to the rest of the termination device. For example, the locking feature may be frangibly connected to the termination device, so that it can be detached from the termination device by breaking the connection between the locking feature and more proximal portion of the body of the termination device. Thus, the locking feature e.g., tube, clamp, knot, etc.) can be attached to the rest of the termination device so that it can be separated. The locking feature may be detachably connected to the rest of the termination device by any appropriate method. Thus, the locking feature (or a portion of the locking feature) may include a releasably attachment region. The releasable attachment region may include any region that can be separated or broken to release the locking feature from the elongate body of the termination device. For example, the releasable attachment region may comprise a region where the locking feature is fused to another region of the termination device (e.g., the distal region of the elongate body).

[0174] In some variations the locking feature is fused by melting the materials comprising at least a portion of the locking feature and a portion of the rest of the termination device. The two materials may be fused together to different degrees (e.g., by varying the number of fuse spots or area of fusing) to adjust the force necessary to separate the two regions of the termination device. The different regions of the termination device may comprise different materials, or may comprise the same material. In some variations, the fused region comprises a third material used to secure the two regions together until they are separated. Being able to use different materials for different regions of the termination device may be advantageous if there are different material requirements for the different regions of the termination device, for example if the more distal portion of the termination device needs to be more flexible, and the more proximal region needs to be stiffer, or vice-versa.

[0175] In some variations, the detachable locking feature of the termination device is attached to the rest of the termination device by a releasable attachment region that has been structurally weakened between the locking feature and the rest of the termination device. For example, the termination device may comprise a scored, etched, perforated, fractured, creased, slotted or dimpled region between the locking feature and the rest of the termination device. An example of a perforated region 3120 is shown in FIG. 39. Thus, the locking feature may be

friction fit. Further, the amount of force and the way that force is applied to detach the locking feature may be controlled to prevent damage to the locking feature, the tether, the anchors, and/or the surrounding tissue. The locking feature may also be released by cutting the joint between it and the rest of the termination catheter (e.g., by a shearing blade that slides to shear the fuse joint). A cutter may also cut the cable and the joint in a combined manner, thus completely releasing the locking mechanism with the cable severed.

[0177] Although we have described only a few of the ways that a locking feature may be detachably connected to a termination device, it should be understood that any appropriate attachment may be used, including snap fits and attachment mechanisms (e.g., threads, etc.). The attachments described herein may be readily scaled in size for use with even applications requiring very small locking features (e.g., during percutaneous applications).

[0178] In operation (e.g., during an annuloplasty procedure), a locking feature is typically secured to the tether to fix its length (in some cases cinching the tether), such that the end of the tether does not slide through the eye of the most proximal anchor, as described above. After the tether is locked, the excess length of tether may be cut and removed.

[0179] Typically, cinching occurs by applying tension to the tether while bracing the termination device (e.g., including a locking feature) against the most proximal anchor. The tether may slide through the termination device when the locking feature is not in a secured state. After the desired amount of cinching is achieved, the locking feature is engaged, locking the suture in place. For example, the termination device shown in FIG. 39 can be used to secure a tether (e.g., cinching an annulus) by applying force from a push rod to push the plug 3913 into the locking feature and secure the tether. The end of the locking feature shown in FIG. 39 comprises an outer tube that is partially or completely closed (narrowed) so as the plug is pushed in, it is held securely against the tether. As described above, the plug may comprise a material which is compressible or elastic to aid in locking the plug into the end of the locking feature. In some variations, a portion of the locking feature may be configured to secure the locking feature in the locked position, and/or to secure the tether. For example, the plug 3913 shown as part of the locking feature in FIGS. 39 and 40 may have polygonal (e.g., hexagonal) sides that interact with the inner surface of the locking mechanism. The plug maybe solid or hollow. The plug may have bumps, dimples, ribs, grooves or holes on the surface to increase traction on the cable. The locking feature may also include structures (e.g., rims, brackets, etc.) to help hold the plug in the locked configuration. Thus, this locking feature (like most of the locking features

can be readily cut by the cutting tube when the tube is brought forward (e.g., moving the cutting tube distally). In FIG. 40A, the cutting tube has at least one edge (e.g., over half of the cutting tube circumference) so that at least one end of the tether (e.g., the end contacting the more proximal end of the tether) is cut by the cutting tube. As described above, other types of tether cutters may be used as well. For example, FIG. 40B shows a similar tether cutter that is configured to cut the tether when the cutting tube 4010 is drawn proximally. In FIG. 40B, the cutting tube has a passage 4012 through which the tether 3910 passes, and at least a portion of the cutting tube is sharp 4014. The tether 3910 also passes through the wall of the termination device (configured as a catheter in FIGs. 40A and 40B). The end of the tether can be cut by drawing the tether taught after securing the locking feature of the termination device and then moving the cutting tube against the tether so that it is cut.

[0182] The exemplary termination devices shown in FIGs. 39 and 40 include passages or holes through which the tether may couple with the tether 3910. As described above, the tether may be threaded into the passages of the termination device either during use, or before inserting the termination device. The locking device portion of a termination device may include a first passage for engaging the tether on the side (e.g., a more distal side, as shown in FIG. 42A and 42B) of the locking device, rather than at the distal end, as shown in FIGS. 39-41. In variations of the locking feature where the side is longer than width, and the tether enters the locking feature from the side, the locking feature may be held against the tissue on the longer side of the locking feature. Thus, the location where the tether first engages the locking feature may determine how the locking feature is positioned after being secured to a cinched tether.

[0183] In some variations, a threading device (e.g., a lasso) may be included to draw the thread through the termination device, as described above for FIG. 14A and 14B. FIG. 41A shows another variation of a threading device 4104, preloaded into the termination device 4101. The threading device shown comprises a wire that forms a loop (e.g., a lasso), and the flattened loop passes through the holes (or passages) in the termination device. The tether may be passed through the loop, and drawn into the termination device, as previously described.

[0184] In some variations, the termination device may include channels, guides or passages which direct the tether. For example, FIG. 41B shows a portion of a termination device having a detachable locking feature 4107. The termination device includes passages and guides which position the tether within the termination device when the tether is coupled to the termination device. Thus, the tether may be held so that it can be secured, and then cut, using

CLAIMS

What is claimed is:

1. A termination device for locking an implantable and cinchable tether, the termination device comprising:
   an elongate body; and
   a locking feature releasably attached to the distal end of the elongate body, the locking feature configured to couple to the tether; the locking feature having an unsecured state, wherein the tether may move with respect to the locking feature, and a secured state, wherein the tether is secured by the locking feature.

2. The termination device of claim 1, further comprising a tether cutter.

3. The termination device of claim 2, wherein the tether cutter is located distally to the locking feature.

4. The termination device of claim 2, wherein the tether cutter is located proximal to the locking feature.

5. The termination device of claim 2, wherein the tether cutter comprises a cutting tube within the elongate body.

6. The termination device of claim 1, wherein the elongate body is configured as a catheter.

7. The termination device of claim 1, further comprising a force applicator for releasing the locking feature from the rest of the termination device.

8. The termination device of claim 7, wherein the force applicator comprises a push rod extending longitudinally within the elongate body of the termination device.

9. The termination device of claim 1, further comprising a releasable attachment region between the locking feature and the elongate body.

an elongate body; and

a locking feature releasably attached to the distal end of the elongate body, the locking feature configured to couple to the tether;

cinching the tether; and

securing the tether with the locking feature.

20. The method of claim 19, further comprising cutting the tether.

21. The method of claim 19, further comprising separating the locking feature from the elongate body.

22. The method of claim 21, wherein the step of separating the locking feature from the elongate body comprises: applying force to separate the locking feature from the elongate body.

23. The method of claim 22, wherein the step of applying force comprises pushing a push rod located at least partly within the elongate body.

24. The method of claim 19, wherein the locking feature is snap-locked to the distal end of the elongate body.

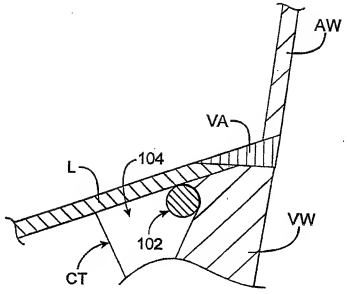


FIG. 2A

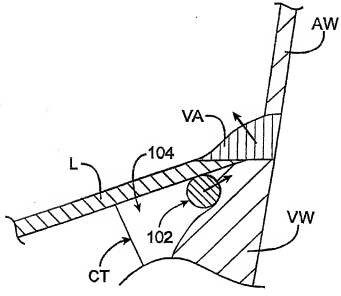


FIG. 2B

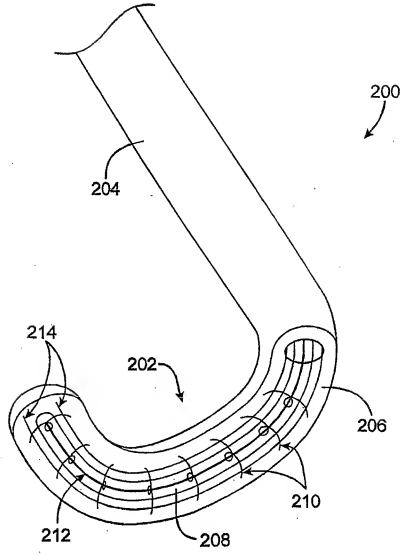


FIG. 3

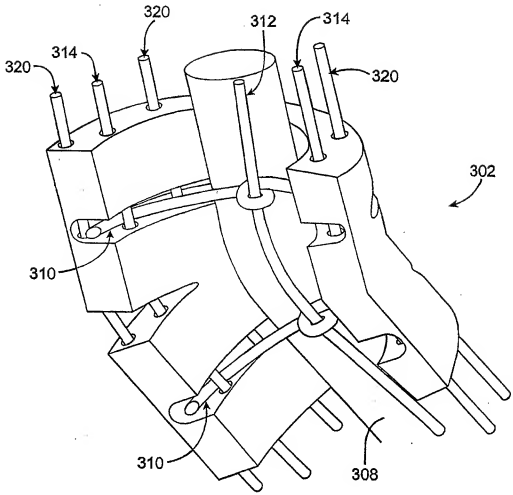


FIG. 5

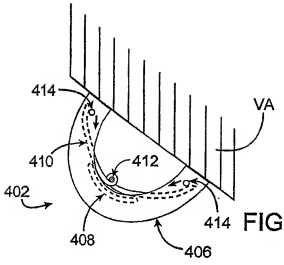


FIG. 7A

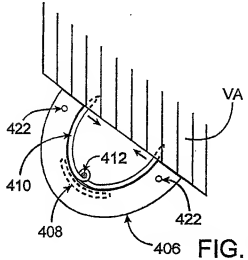


FIG. 7B

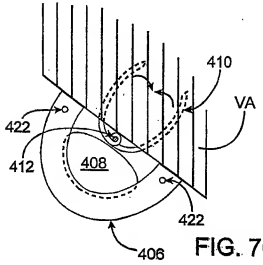


FIG. 7C

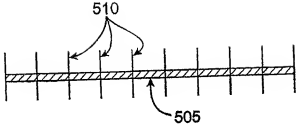


FIG. 8A

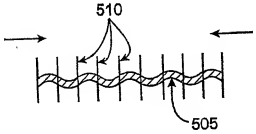


FIG. 8B

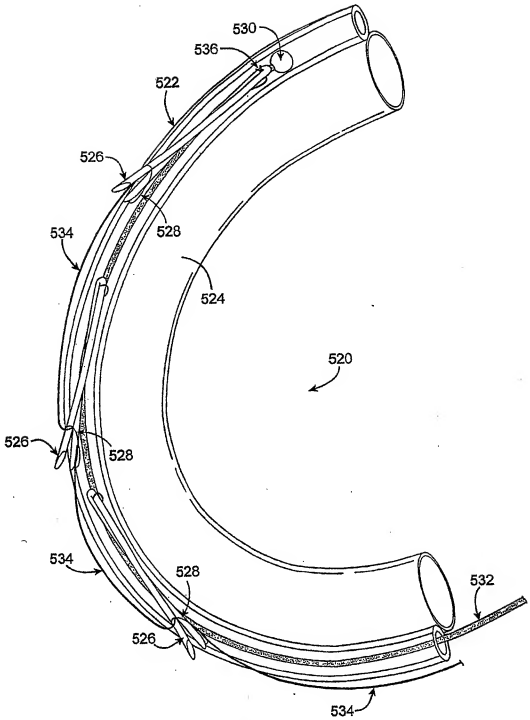


FIG. 9B

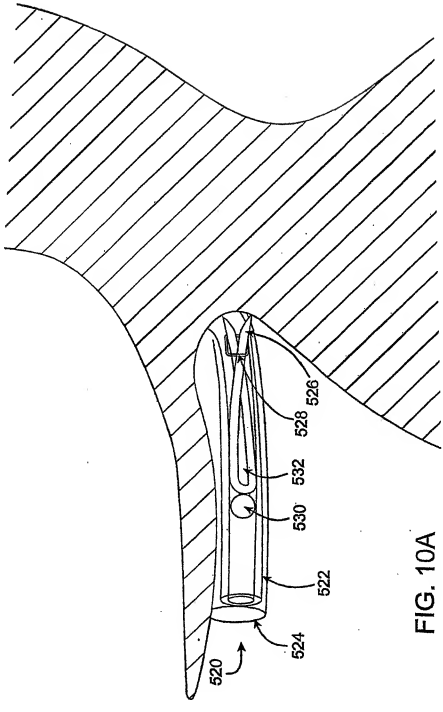


FIG. 10A

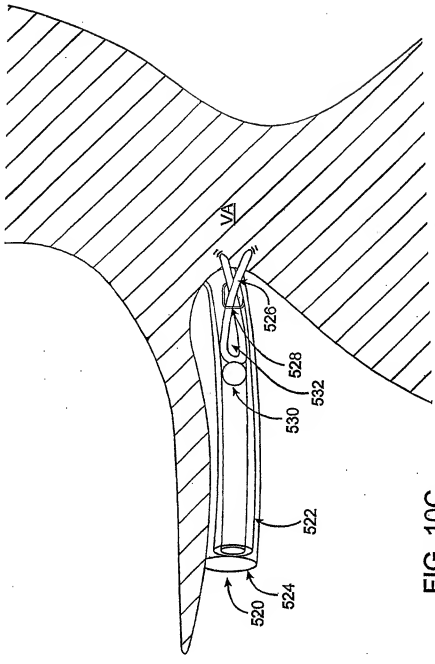


FIG. 10C

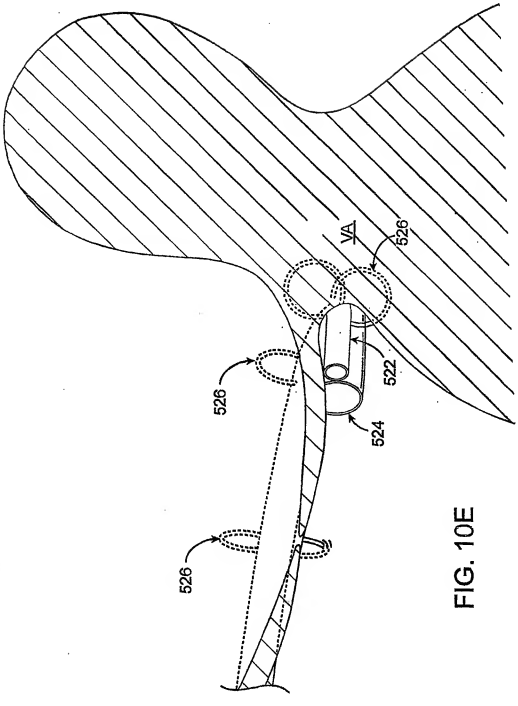


FIG. 10E

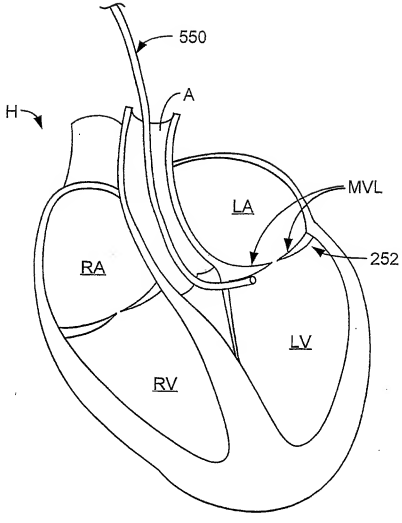


FIG. 11

FIG. 12D

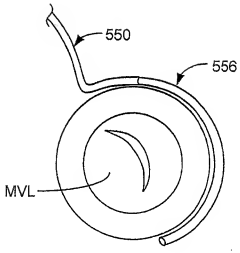


FIG. 12E

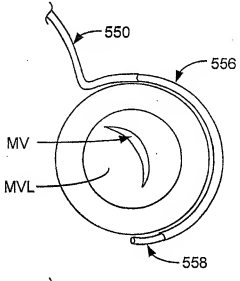
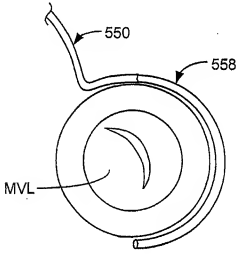


FIG. 12F



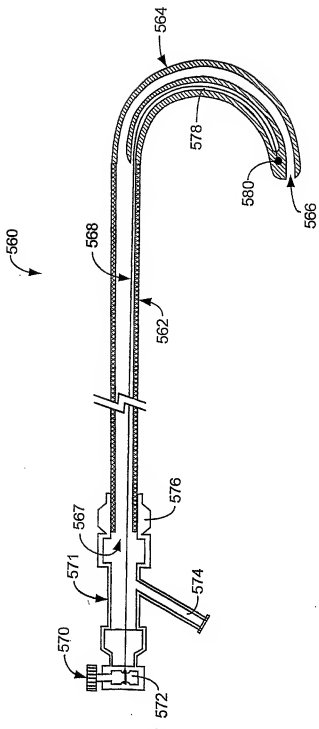


FIG. 13B

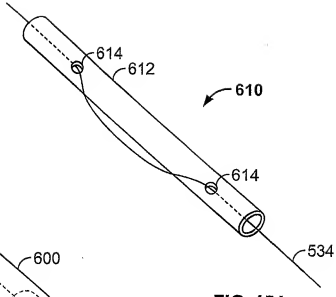


FIG. 15A

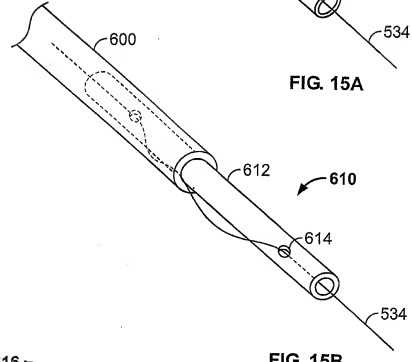


FIG. 15B

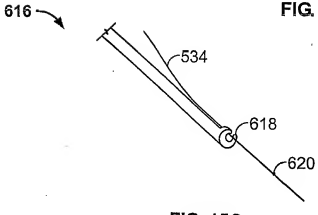


FIG. 15C

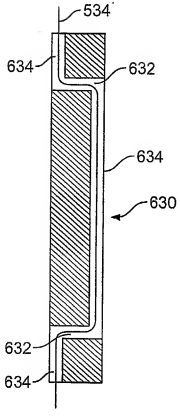


FIG. 15G

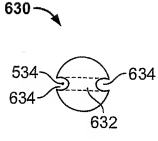


FIG. 15H

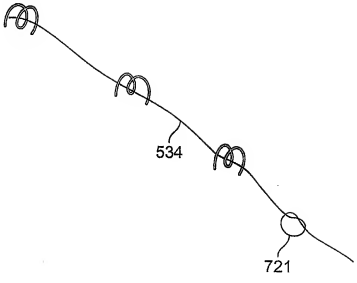


FIG. 16D

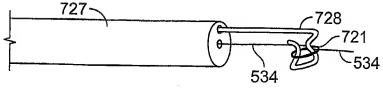


FIG. 16E

FIG. 19A

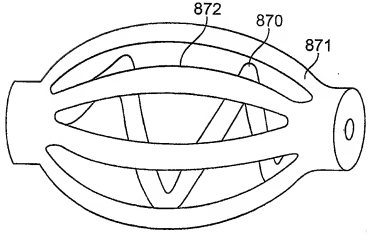


FIG. 19B

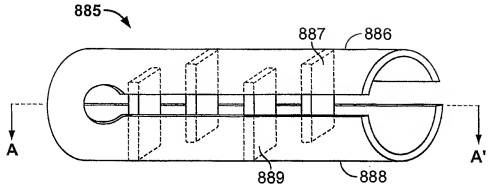


FIG. 21A

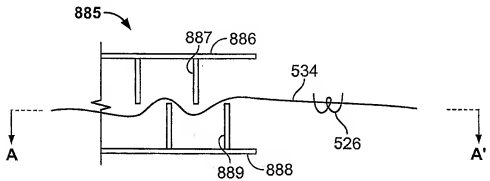


FIG. 21B

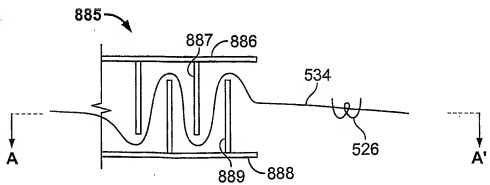


FIG. 21C

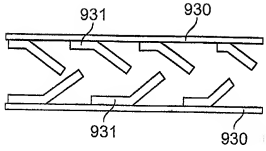


FIG. 24A

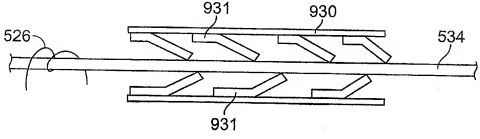


FIG. 24B

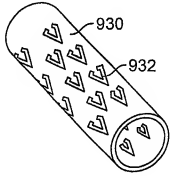


FIG. 25

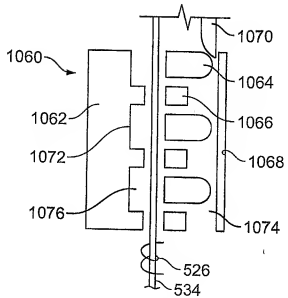


FIG. 28A

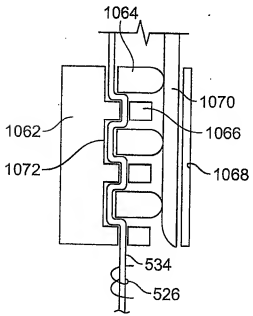


FIG. 28B

FIG. 29C FIG. 29D FIG. 29E

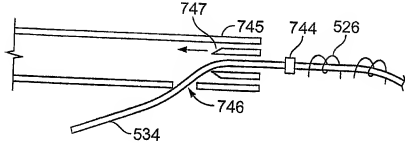


FIG. 29F

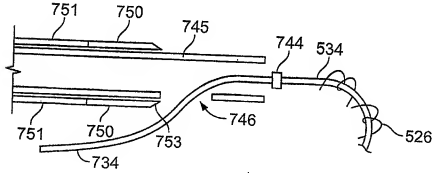


FIG. 30A

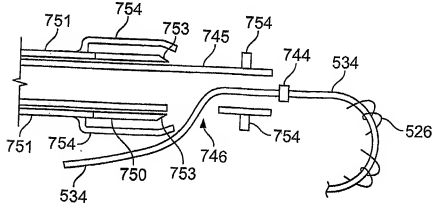


FIG. 30B

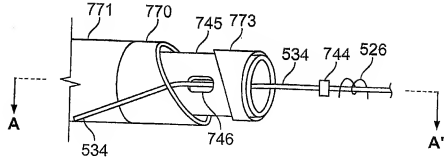


FIG. 32A

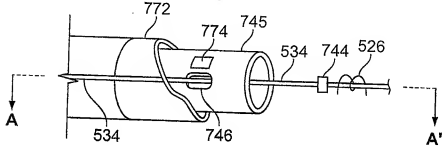


FIG. 32B

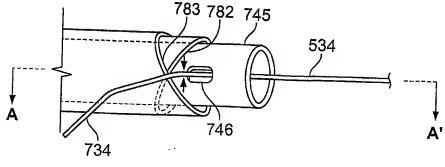


FIG. 33

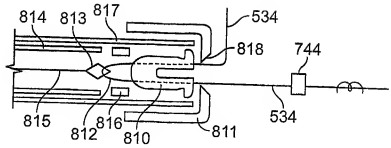


FIG. 35B

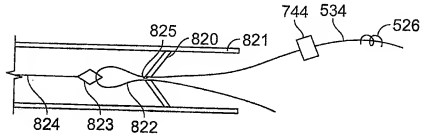


FIG. 35C

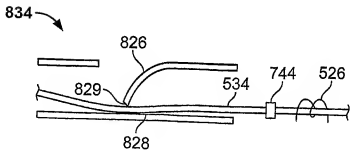


FIG. 36A

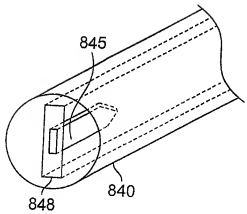


FIG. 38B

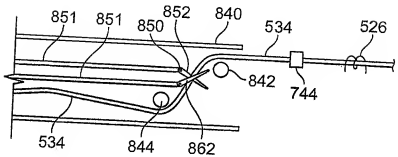


FIG. 38C

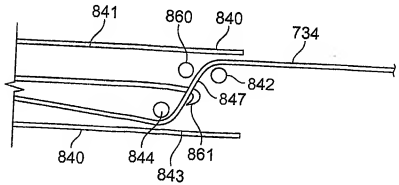


FIG. 38D

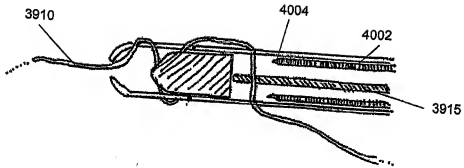


FIG. 40A

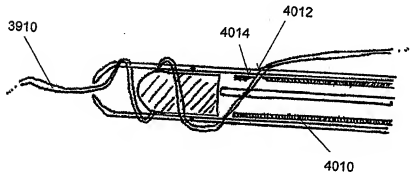


FIG. 40B

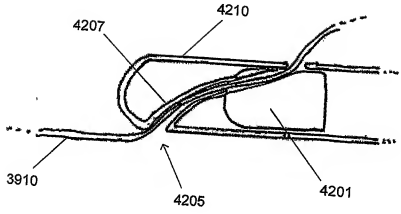


FIG. 42A

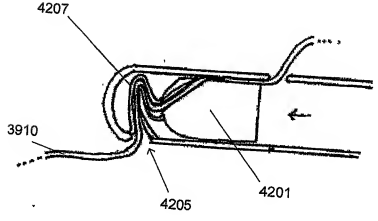


FIG. 42B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/043597

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